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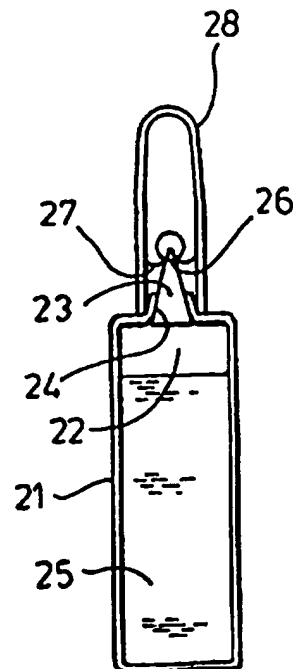
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(21) International Application Number: PCT/GB96/02917 (22) International Filing Date: 26 November 1996 (26.11.96) (30) Priority Data: 9524961.1 6 December 1995 (06.12.95) GB 9616359.7 3 August 1996 (03.08.96) GB (71) Applicant (for all designated States except US): GILGRASCRIP LIMITED [GB/GB]; 249 West George Street, Glasgow G2 4RB (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): McMAHON, Keith, Herd, Younie [GB/GB]; 19 Mitchell Walk, Rosyth, Fife KY11 2RQ (GB). (74) Agents: McNEIGHT, David, Leslie et al.; McNeight & Lawrence, Regent House, Heaton Lane, Stockport, Cheshire SK4 1BS (GB).			(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: AMPOULE SYSTEM

(57) Abstract

There is disclosed an ampoule comprising an outlet and a closure therefor which seals against a seat of the outlet so that the outlet is opened to access the ampoule contents by inward movement of the closure, and retaining means to retain the closure in sealing relation with the outlet until access is required.



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## **AMPOULE SYSTEM**

This invention relates to an ampoule and a system including a syringe that may incorporate such an ampoule.

Ampoules containing drugs and other substances for injection or for administration in some other fashion conventionally comprise a glass phial, containing, say, 5 ml of liquid, with an integral cap, heat-sealed in glass-blowing fashion, with a snap line where the cap can be broken off to access the contents. This requires skill and care so as not to spill the contents or cause injury to the user or contaminate them. The loading of a syringe with the contents for injection and the safe disposal of the sharp edged phial and cap are separate problem areas.

Plastic ampoules with a cut-off or twist-off cap have most of these problems, and are not suitable for all substances.

The present invention provides an improved ampoule and a system including a syringe which does not suffer from the problems referred to.

According to the present invention there is provided an ampoule comprising an outlet and a closure therefor which seals against a seat of the outlet so that the outlet is opened to access the ampoule contents by inward movement of the closure, and retaining means to retain the closure in sealing relation with the outlet until access is required.

The outlet may be circular and the seat conical, the closure also being conical to seal against the seat.

The closure/seat seal may be a glass-to-glass seal.

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The retaining means may comprise a detent on the closure and release means normally holding the closure in sealing relationship with the seat by engagement with the detent to prop the closure against the ampoule.

The detent may comprise a ball or like arrangement on the closure.

The ampoule may comprise a removable sheath normally covering the outlet and closure.

The sheath may comprise said retaining means releasably to retain the closure in sealing relation with the outlet. The sheath may have spring latch means engaging a detent on the closure to prop the closure against the ampoule.

The sheath may sterile-seal the outlet and closure.

The closure may have a post-like extension projecting outwardly from the ampoule, the post-like extension having a portion of reduced cross-sectional area on the outside of the ampoule whereby initial inward movement allows the contents of the ampoule to be discharged through the relieved part of the portion of reduced cross-sectional area and further inward movement causes the outlet to be closed by the outer part of the post-like extension.

The retaining means may comprise a cap over the end of the ampoule and having an aperture therein through which the post-like extension passes.

The ampoule may be combined with the barrel of an hypodermic syringe, the ampoule forming the plunger of the syringe and slidably sealing with the interior of the barrel, the free end of the post-like extension initially engaging the base of the barrel, depression of the ampoule causing the post-like extension to move into the ampoule

initially transferring the contents of the ampoule to the barrel and then discharging the contents from the barrel through the needle of the syringe.

The post-like extension may be hollow with an open outer end to enable it to accommodate the needle under the action of a needle retraction mechanism at the end of the injection stroke of the ampoule.

The ampoule may be divided into a plurality of compartments each provided with an outlet and closure.

Embodiments of ampoules and a system according to the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a section through a conventional prior art ampoule;

Figure 2 is a section through a first embodiment of ampoule according to the invention;

Figure 3 is a series of sections through a second embodiment of ampoule and a syringe working therewith in successive stages of deployment;

Figure 4 is a section through a third embodiment of ampoule forming part of a syringe;

Figure 5 is a section through a fourth embodiment of ampoule forming part of a syringe;

Figure 6 is a cross-section through the syringe on the line VI-VI of Figure 5; and

Figure 7 shows a perspective view of an ampoule for use in a syringe, but comprising two compartments.

The conventional prior art 5 ml ampoule 11 commonly used worldwide is shown in Figure 1. It is of glass with an integral cap 12, heat-sealed at 13 in glass-blowing fashion, with a snap line 14 where the cap 12 can be broken off to access the contents 15.

Figure 2 illustrates a first form of ampoule 21 according to the invention again of glass with an outlet 22 and a closure 23 therefor which seals against an inwardly facing seat 24 of the outlet 22 so that the outlet 22 is opened to access the ampoule contents 25 by inward movement of the closure 23, and retaining means 26 to retain the closure 23 in sealing relation with the outlet 22 until access is required.

The outlet 22 is circular and the seat 24 is conical, the closure 23 also being conical to seal against the seat. The closure/seat seal is a glass-to-glass seal, clearly, when the ampoule and closure are made of glass - a plastics equivalent can be used if the plastic is suitable for the contents.

To prevent the closure 23 from simply falling into the ampoule retaining means are provided comprising a detent 26 on the closure 23 and release means 27 normally holding the closure in sealing relationship with the seat 24 by propping the detent 26 so as to hold the closure 23 against the ampoule. The detent 26 comprises a ball enlargement on the closure 23. This embodiment has a removable sheath 28 e.g. of plastics material normally covering the outlet and closure - and performing, where required, the vital function of sterile-sealing the outlet 22 and closure 23 which latter, on

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opening, falls into the ampoule when it could, otherwise, contaminate the contents - comprising the release means 27 in the form of spring latch means engaging the detent 26 on the closure 23 to prop the detent against the ampoule. When the sheath 28 is pulled off, the spring latch means are pulled over the ball detent 27 to release the closure 23 to fall into the ampoule, to access the contents 25.

Figure 3 illustrates a system using an ampoule basically similar to that of Figure 2, like parts being indicated by like reference numerals.

As shown in Figure 3a, the closure 23 has a post-like extension 30 projecting outwardly from the ampoule. The extension 30 has a portion 31 of reduced cross-sectional area on the outside of the ampoule. The retaining means comprises a cap 32 which fits over the end of the ampoule and around the closure 23 normally to hold the closure in sealing position.

In use the sheath 28 is removed (Figure 3b) and the ampoule inserted into the barrel 40 of a syringe, the cap 32 forming a piston ring slidably and sealingly engaging the inner wall of the barrel 40.

Depression of the ampoule brings the extension 30 into abutment with the base of the barrel 40 and lifts the closure 23 from the seat to allow the contents of the ampoule to flow through the portion 31 into the body of the barrel (Figure 3c). Continued depression enables the cap 32 to seal around the distal part of the extension 30 and expel the contents of the barrel 40 through the needle hub 41 in known manner (Figure 3d).

Referring now to Figure 4, it will be seen that a syringe comprises, in known manner, a barrel 50 whose closed end wall 51 is provided with a needle mount 52 carrying a hypodermic needle 53, and a plunger 54, slidable within the barrel 50.

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The plunger 54 is an ampoule embodying the invention and has an aperture 55 in its base 56 which is sealingly slidable along a post 57 extending axially within the barrel from its end wall 51.

The post 57 is of solid section and has a portion of relieved cross-section in the form of a waist 58 adjacent the base of the plunger 54 when in its raised position (as shown in Figure 4).

The interior of the plunger 54 defines a compartment which is pre-filled at the time of manufacture with a liquid to be administered.

Friction between the plunger 54 and barrel 50 retains the plunger in position until use.

In use, as the plunger is depressed, the aperture 55 passes over the waist 58 to establish a communication between the interiors of the plunger 54 and barrel 50. The liquid flows into the barrel 50. Continued movement of the plunger 54 takes the aperture 55 past the waist 58 to seal the interior of the plunger 54 from the barrel 50 and enable the liquid to be discharged through the needle 53 for injection in known manner.

The post 57 is laterally off-set from the needle mount 52 and the base 56 of the plunger is provided with a frangible disc 59 to permit entry of the needle 53 into the interior of the plunger at the completion of its stroke under the action of a spring operated needle retraction mechanism of known kind.

The compartment defined by the interior of the barrel may itself be pre-loaded with a solid substance, for example in the form of a powder, or liquid, which mixes with and if solid dissolved by the liquid prior to injection.



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Referring now to Figures 5 and 6 it will be seen that the further form of syringe is generally similar to that of Figure 4, like parts being numbered with like reference numerals.

In this example, however, the post 57 is hollow and co-axial with the needle 53. Slits 60 at the base of the post provide a passage for the liquid to the needle as the injection proceeds. A spider 61 is located within the post 57 and has lugs 62 extending through the slits 60. At the completion of the downward stroke of the plunger 54 its base engages the lugs 62 to force the spider 61 against the needle mount 52 to operate a needle retraction mechanism of known kind to expel the needle into the interior of the post, the centre of the spider breaking free from the lugs as this takes place.

It will be appreciated that it is not intended to limit the invention to the above examples only, many variations, such as might readily occur to one skilled in the art, being possible without departing from the scope thereof as defined by the appended claims.

Thus, and as shown in Figure 7, an ampoule for use in a syringe might have more than one compartment, in this example two, each with its own closure, an alternative approach to the administration of different drugs simultaneously, or combining different constituents at the time of delivery.

## **CLAIMS**

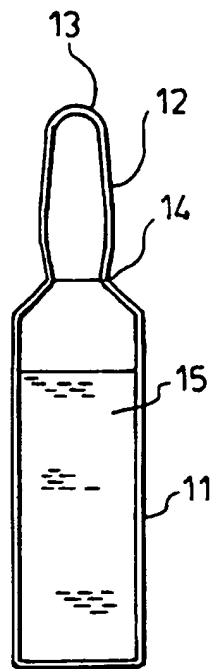
1. An ampoule comprising an outlet and a closure therefor which seals against a seat of the outlet so that the outlet is opened to access the ampoule contents by inward movement of the closure, and retaining means to retain the closure in sealing relation with the outlet until access is required.
2. An ampoule according to claim 1, in which the outlet is circular and the seat is conical, the closure having a conical portion to seal against the seat.
3. An ampoule according to claim 1 or claim 2, in which the closure/seat seal is a glass-to-glass seal.
4. An ampoule according to any one of claims 1 to 3, in which the retaining means comprise a detent on the closure and release means normally holding the closure in sealing relationship with the seat by engagement with the detent to prop the closure against the ampoule.
5. An ampoule according to claim 4, in which the detent comprises a ball or like enlargement on the closure.
6. An ampoule according to claim 4 or 5 having a sheath normally covering the outlet and closure which sheath comprises said release means releasably to retain the closure in sealing relation with the outlet.
7. An ampoule according to claim 6, in which the sheath has spring latch means engaging a detent on the closure to prop the closure against the ampoule.

8. An ampoule according to any one of claims 1 to 5, comprising a removable sheath normally covering the outlet and closure.
9. An ampoule according to any one of claims 6 to 8 in which the sheath sterile-seals the outlet and closure.
10. An ampoule according to any one of claims 1 to 3, wherein the closure has a post-like extension projecting outwardly from the ampoule, the post-like extension having a portion of reduced cross-sectional area on the outside of the ampoule whereby initial inward movement allows the contents of the ampoule to be discharged through the relieved part of the portion of reduced cross-sectional area and further inward movement causes the outlet to be closed by the outer part of the post-like extension.
11. An ampoule according to claim 10, wherein the retaining means comprises a cap over the end of the ampoule and having an aperture therein through which the post-like extension passes.
12. An ampoule according to claim 11, in combination with the barrel of an hypodermic syringe, the ampoule forming the plunger of the syringe and slidingly sealing with the interior of the barrel, the free end of the post-like extension initially engaging the base of the barrel, depression of the ampoule causing the post-like extension to move into the ampoule initially transferring the contents of the ampoule to the barrel and then discharging the contents from the barrel through the needle of the syringe.
13. An ampoule according to claim 12, wherein the post-like extension is hollow with an open outer end to enable it to accommodate the needle under the action of a needle retraction mechanism at the end of the injection stroke of the ampoule.

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14. An ampoule according to any one of claims 11 to 13, divided into a plurality of compartments each provided with an outlet and closure.

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(PRIOR ART)

FIG. 1

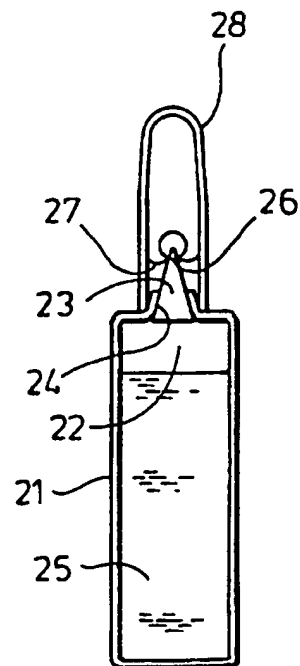
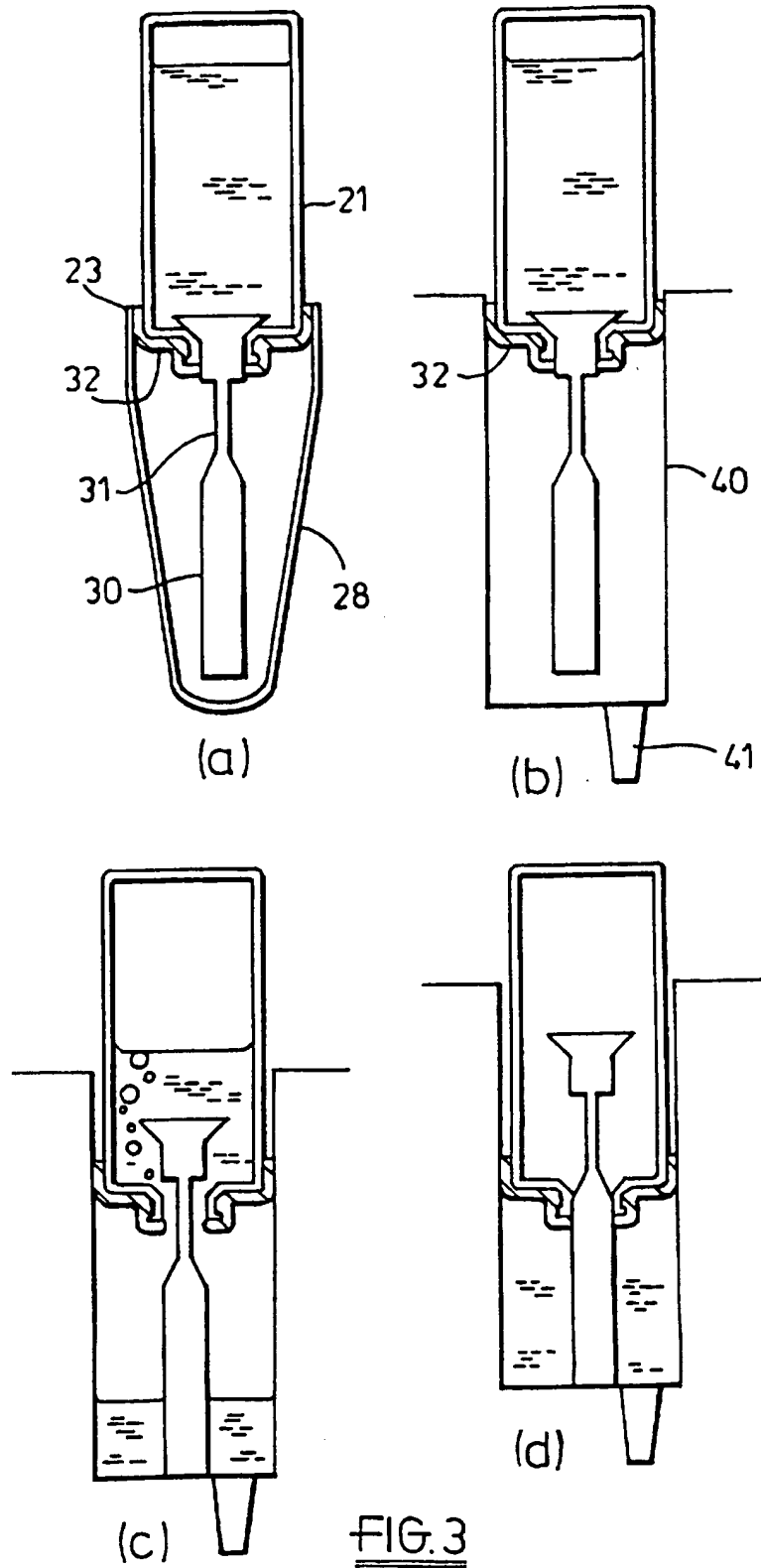


FIG. 2

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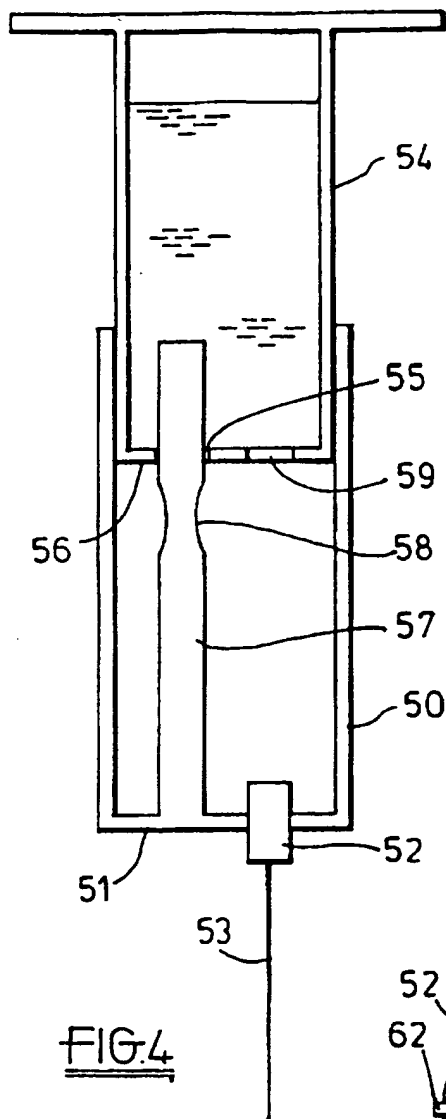


FIG. 4

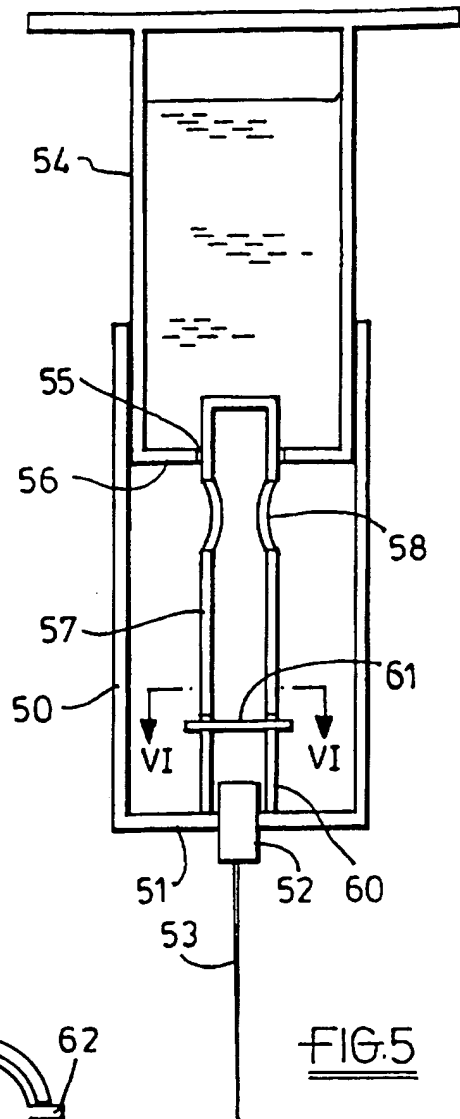


FIG. 5

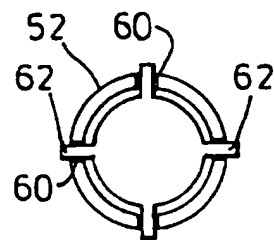


FIG. 6

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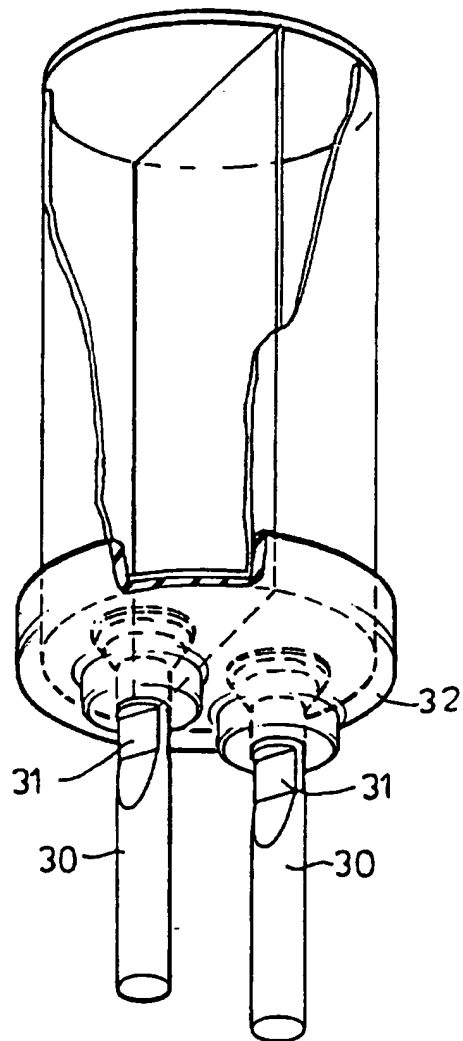


FIG. 7



# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB 96/02917

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61J1/06 A61M5/24

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61J A61M B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 232 207 A (LEWIS WOOLF GRIPTIGHT LTD.) 27 December 1974	1,8,9
A	see the whole document	4,6
A	CH 414 953 A (CIBA AG.) 30 December 1966 see page 2, line 21 - line 36; figures	1,2
A	FR 349 516 A (GAILLOT) 2 June 1905 see the whole document	10,12
A	US 3 506 006 A (LANGE) 14 April 1970 see figures	12

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

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FR 2232207 A	27-12-74	NONE	
CH 414953 A		NONE	
FR 349516 A		NONE	
US 3506006 A	14-04-70	NONE	